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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCT 21035Y		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. / 503/10867	International filing date (day/month/year) 08 April 2003 (08.04.2003)	Priority date (day/month/year) 11 April 2002 (11.04.2002)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/415 and US Cl.: 514/405; 548/359.1			
Applicant MERCK & CO., INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 10 November 2003 (10.11.2003)		Date of completion of this report 12 January 2004 (12.01.2004)	
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230		Authorized officer <i>Valerie Bell-Harris</i> Rei-tsang Shiao Telephone No. 571/272-1600	

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-159 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 160-232, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the drawings:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

Please See Continuation Sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-24 (in part)

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-24 (in part)</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-24 (in part)</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-24 (in part)</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

----- NEW CITATIONS -----

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No
Patent No.
US 4,349,559

Publication Date
(day/month/year)
14/Sept/1982

Filing Date
(day/month/year)
19/02/1981

Priority date (valid claim)
(day/month/year)

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure referring to
non-written disclosure
(day/month/year)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

IV. 3. This Authority considers that the requirement of unity of invention is accordance with Rules 13.1, 13.2 and 13.3 is not complied with for the following reasons:

- I Claims 1-24, in part, drawn to products of formula I, wherein K is NR3 and J is NR1, L is C(R5)(R6), and R1, R3, R5, and R6 are not HET or alkyl-HET; X, Y, R7, R8, R10, R11, and R12 are not HET or alkyl-HET; and their methods of use.
- II Claims 1-24, in part, drawn to products of formula I, wherein L is NR5 and J is NR1, K is C(R3)(R4), and R1, R3, R4, and R5 are not HET or alkyl-HET; X, Y, R7, R8, R10, R11, and R12 are not HET or alkyl-HET; and their methods of use.
- III Claims 1-24, in part, drawn to products of formula I, wherein K is NR3 and J is NR1, L is C(R5)(R6), and R1, R3, R5, and R6 are not HET or alkyl-HET; X, Y, R7, R11, and R12 are not HET or alkyl-HET; and R8 or R10 is thiazole; and their methods of use.
- IV Claims 1-24, in part, drawn to products of formula I, wherein K is NR3 and J is NR1, L is C(R5)(R6), and R1, R3, R5, and R6 are not HET or alkyl-HET; X, Y, R7, R11, and R12 are not HET or alkyl-HET; and R8 or R10 is pyridine; and their methods of use.
- V Claims 1-24, in part, drawn to products of formula I, and not embraced in Group I-IV; and their methods of use.

Claims 1-24 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 state that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex. B, Part I(b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part I(e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(I) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or

(II) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or

(III) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process..."

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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/ 503/10867**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

In accordance with 37 C.F.R. 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Claims 1-24 are generic to a plurality of disclosed patentably distinct species comprising for example, the compounds designated as (1) a compound 1, 2 diazole tricyclo ring system not having other heterocycle ring, (2) compound 1, 3 diazole tricyclo ring system not having other heterocycle ring, (3) a compound 1, 2 diazole tricyclo ring system having another heterocycle ring thiazole, (4) a compound 1, 2 diazole tricyclo ring system having another heterocycle ring pyridine.

The inventions do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features that defines a contribution over the prior art. The compounds claimed contain benzindazole moiety, which does not define a contribution over the prior art (as can be seen by the compound I of CAS:113:152403). Each of the inventions in this applications represent a discrete compound which one skilled in the art which beside sharing no structural element, cannot be said to belong to a recognized class of chemical compounds. Accordingly, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.